REMARKS

Claims 37, 39, 41-46, 54-55, 58, 65, and 83-96 are pending in the present application. By virtue of this response, claim 37 has been amended, claims 40, 56-57, 59-60, and 66-82 have been cancelled, and new claims 83-96 have been added. Support for the new claims can be found throughout the specification, for example, at page 9, lines 17-28; page 10, line 31 to page 11, line 14; page 12, lines 18-28; page 15, lines 13-29; and the Examples. No new matter has been introduced. Accordingly, claims 37, 39, 41-46, 54-55, 58, 65, and 83-96 are currently under consideration.

Newly added claims 83-96 recite an antibody having the sequence of six hypervariable regions (SEQ ID NO:5-10).

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claimed subject matter in future continuation, continuation-in-part, and/or divisional applications.

Claim Rejections – 35 U.S.C. § 112, First paragraph

(a) Enablement

Claims 37, 39-46, 54-60, 65, 69-71 and 73-82 are rejected under 35 U.S.C. 112, first paragraph, as allegedly not being enabled by the specification. According to the Examiner, the specification does not provide enablement for administering variants of SEQ ID NO: 2 or 4, nor for the prophylactic treatment. However, the Examiner states that the specification is enabled for "a method for reducing tissue factor (TF) levels to treat a solid tumor exhibiting TF expression, comprising administering to a mammal having the tumor a therapeutically effective amount of antibody that comprises the amino acid sequence of SEQ ID NO:2 or SEQ ID NO:4, or fragment thereof that binds native human tissue factor to form a complex, whereby Factor X binding to the complex is inhibited, and Factor VII or VIIa binding to tissue factor is not inhibited."

Further, the Examiner explicitly acknowledges that "amending the claim to recite 'a mammal having the tumor' would obviate the rejection" and that the specification is enabled for a method for reducing tissue factor levels comprising administering an antibody comprising SEQ ID NO: 2 or 4 or fragment therefore that binds native human tissue factor to form a complex.

Applicants respectfully traverse this rejection. However, for the sake of expediting prosecution and not in acquiescence to the propriety of the Examiner's rejection, claims 37 has been amended to recite the subject matter that the Examiner states is enabled by the specification and to incorporate the limitation that the Examiner states would obviate the rejection. As such, Applicants maintain that claim 37 is fully enabled. By virtue of its dependency on claim 37, claims 39, 41-46, 54-55, 58, and 65 are also fully enabled. Claims 69-71 and 73-82 have been cancelled, thus rendering the rejection of these claims moot.

In view of the foregoing, Applicants submit that the claims are fully enabled and respectfully request that the Examiner withdraw this rejection.

(b) Written Description

Claim 69

Claim 69 is rejected under 35 U.S.C 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that the specification does not provide support for the claimed invention of an anti-tissue factor antibody derived from the amino acid sequence of SEQ ID NO: 2 or 4, or fragment thereof.

Without acquiescing to the propriety of this rejection and for purposes of expediting prosecution, claim 69 has been cancelled, thus rendering the rejection of this claim moot.

Claims 69-71 and 73-82

Claims 69-71 and 73-82 are also rejected under 35 U.S.C 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that "the claim language encompasses anti-TF antibodies comprising variants of SEQ ID NO: 2 or 4 and such variant antibodies exhibit the recited properties."

Without acquiescing to the propriety of the Examiner's allegations, Applicants have cancelled claims 69-71 and 73-82, thus rendering this rejection moot.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection.

Claim Rejections – 35 U.S.C. § 112, Second paragraph

Claim 69, 71, and 75 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The Examiner states that term, "derived from," in claim 69 is not defined in the specification and that the recitation of the phrase, "identifying characteristic of H36.D2.B7 deposited as ATCC HB-12255," is unclear with respect to what the identifying characteristics are. The Examiner further states that the feature of "wherein the chimeric antibody" recited in claim 75 lacks antecedent basis.

Claims 69, 71, and 75 have been cancelled, thus obviating the rejection. Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of these claims.

Claim Rejections – 35 U.S.C. § 102(b)

Claims 69, 73, and 78-82 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Edgington et al. (U.S. Patent NO: 5,223,427 ("the '427 patent)). The Examiner contends that the '427 patent teaches a method of treating a human patient having tumor cells by administering an anti-TF monoclonal antibody (MoAb) linked to an anti-tumor agent and that these anti-TF MoAbs immunoreact with human TF, such as TF8-11D12, with the property of blocking access of Factor X to the formed complex of TF and Factor VIIa, and inhibiting Factor IX and X activation, as characterized by Fiore et al. (Blood, 1992, Vol. 80(12): 3127-3134).

Without acquiescing to the propriety of this rejection and for purposes of expediting prosecution, Applicants have canceled claims 69, 73, and 78-82, thus rendering this rejection moot.

The newly submitted claims are not anticipated by the '427 patent. The antibodies claimed in the present invention are different from the MoAbs disclosed in the '427 patent.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection.

Claim Rejections – 35 U.S.C. § 103

Claims 74-77 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over the '427 patent, in view of Queen et al. (U.S. Patent NO: 5,693,762 (the '762 patent)). The Examiner states that the anti-TF MoAbs disclosed in the '427 patent in view of the chimeric and humanized antibodies with mouse variable regions joined to human constant regions as disclosed in the '762 patent. He therefore alleges that one skilled in the art would have been able to generate the humanized, chimeric, or the single chain anti-TF antibody in view of these references and also would have been motivated to combine the teachings of these references.

Without acquiescing to the propriety of this rejection and for purposes of expediting prosecution, Applicants have canceled claims 74-77, thus rendering the rejection of these claims moot.

The newly submitted claims are not rendered obvious by the '427 patent in view of the '762 patent. The antibodies claimed in the present invention are different from the MoAbs disclosed in the '427 patent.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw the rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 146392002520. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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